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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,434	02/15/2005	Rene Djurup	DJURUP1	4128
1444 7590 06/19/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER GUDIBANDE, SATYANARAYAN R	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 06/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/524,434

Applicant(s)

DJURUP ET AL.

Examiner

Satyanarayana R. Gudibande

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 27-40, 53, 54, 57, 58 and 73 is/are pending in the application.
- 4a) Of the above claim(s) 28-38, 40, 54, 57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 39, 53 and 73 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/21/05, 3/2/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of group I invention (claims 1, 27-40, 53 and 73) and SEQ ID NO. 595 as species in the reply filed on 4/30/07 is acknowledged. It should be noted that applicants state that the elected species read on claims 1-20, 22-27, 48, 49 and 53. However, claims 2-26, 41-52 have been canceled.

Prior art search for the SEQ ID NO: 595 indicated that the peptide sequence SEQ ID NO: 595 was found to be free of art. Search was extended and prior art was found for SEQ ID NO: 594.

Claims 1, 27-40, 53, 54, 57, 58 and 73 are pending.

Claims 28-38 and 40 have been withdrawn from further consideration as being drawn to non-elected species.

Claims 54, 57 and 58 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 2-26, 41-52, 55, 56 and 59-72 have been canceled.

Claims 1, 27, 39, 53 and 73 are examined on the merit.

### ***Claim Objections***

### ***Allowable Subject Matter***

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Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 1 is objected to because of the following informalities: Claim 1 has the word "from" repeated twice within some of the lines that describe the limitations for various 'X' variable such as "X<sup>5</sup> is Thr or selected from **from** Group". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

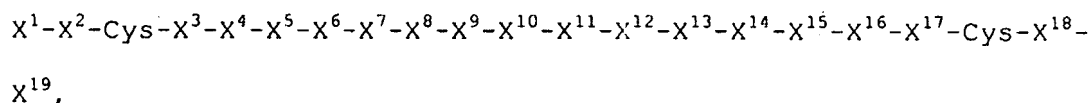
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 39, 53 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Pereira, et al., 1993, PNAS, 90, 4733-4737.

In the instant application applicants claim a peptide having the sequence of at most 44 amino acid residues comprising of the motif of the formula:



wherein,

X can be an amino acid sequence or a single amino acid residue selected either from Group 1 consisting of Ala, Gly, and Ser, Group 2 consisting of Arg and Lys, Group 3 consisting

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of His, Ile, Leu, Met, Phe, Pro, Thr, Val, Trp, and Tyr, Group 4 consisting of Asn and Gln, or Group 5 consisting of Ala, Asn, Arg, Gln, Gly, His, Ile, Leu, Lys, Met, Phe, Pro, Ser, Thr, Trp, Tyr, Val,

wherein  $X^1$  can be represented by a sequence consisting of 2-5 amino acid residues or an amino acid residue selected from Group 2;

$X^2$  is selected from Group 5 or Group 3;

$X^3$ ,  $X^{15}$  and  $X^4$  are selected from Group 1;

$X^5$  is Thr or selected from Group 1;

$X^6$ ,  $X^{11}$ ,  $X^{12}$ ,  $X^{13}$  and  $X^7$  are selected from Group 3;

$X^8$  and  $X^{17}$  are selected from Group 1, 3 or 4;

$X^9$  is selected from Group 5, 1 or 3;

$X^{10}$  is selected from Group 2, 3 or 4;

$X^{14}$  is Ser or selected from Group 3;

$X^{16}$  and  $X^{18}$  is selected from Group 1 or 3

$X^{19}$  can be represented by a sequence consisting of 2-5 amino acid residues or a single amino acid residue selected from Group 5, 2, or 4,

with the proviso, that when  $X^1$  includes Pro, then  $X^{19}$  is Gln.

The reference of Pereira, et al., discloses the following peptide, NQGRHFCCGGALIHARFVMTAASCFQ (abstract) that corresponds to the SEQ ID NO: 594 of the instant application and hence meets the limitation of claim 39. In the peptide NQGRHFCCGGALIHARFVMTAASCFQ,

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$$NLQRH = X^1$$

$$F = X^2$$

$$G = X^3$$

$$G = X^4$$

$$A = X^5,$$

$$L = X^6,$$

$$I = X^7$$

$$H = X^8,$$

$$A = X^9,$$

$$R = X^{10},$$

$$F = X^{11},$$

$$V = X^{12},$$

$$M = X^{13},$$

$$T = X^{14},$$

$$A = X^{15},$$

$$A = X^{16},$$

$$S = X^{17},$$

$$F = X^{18},$$

$Q = X^{19}$  of the formula in claim 1 of instant application. Therefore meets the limitation of the claim 1 of instant application. The peptide was dissolved at 1 mg/ml concentration in sterile endotoxin free water (page 4734, column 2, paragraph 1) and hence suitable as a pharmaceutical composition, thereby meeting the limitation of claim 73. The peptide disclosed by Pereira, et al.,

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is the same as the peptide SEQ ID NO: 594 of the instant application, and therefore inherently possesses the property that is capable of inhibiting the secretion of cytokine IL-6 from monocytes. Therefore meets the limitation of claim 53 of the instant application. Therefore, the cited reference of Pereira anticipates the instant patent application.

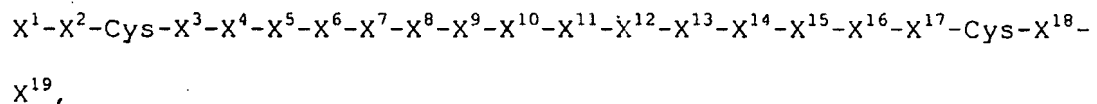
***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 39, 53 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant application applicants claim a peptide having the sequence of at most 44 amino acid residues comprising of the motif of the formula:



wherein,

X can be an amino acid sequence or a single amino acid residue selected either from Group 1 consisting of Ala, Gly, and Ser, Group 2 consisting of Arg and Lys, Group 3 consisting of His, Ile, Leu, Met, Phe, Pro, Thr, Val, Trp, and Tyr, Group 4 consisting of Asn and Gln, or Group 5 consisting of Ala, Asn, Arg, Gln, Gly, His, Ile, Leu, Lys, Met, Phe, Pro, Ser, Thr, Trp, Tyr, Val,

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wherein  $X^1$  can be represented by a sequence consisting of 2-5 amino acid residues or an amino acid residue selected from Group 2;

$X^2$  is selected from Group 5 or Group 3;

$X^3$ ,  $X^{15}$  and  $X^4$  are selected from Group 1;

$X^5$  is Thr or selected from Group 1;

$X^6$ ,  $X^{11}$ ,  $X^{12}$ ,  $X^{13}$  and  $X^7$  are selected from Group 3;

$X^8$  and  $X^{17}$  are selected from Group 1, 3 or 4;

$X^9$  is selected from Group 5, 1 or 3;

$X^{10}$  is selected from Group 2, 3 or 4;

$X^{14}$  is Set or selected from Group 3;

$X^{16}$  and  $X^{18}$  is selected from Group 1 or 3

$X^{19}$  can be represented by a sequence consisting of 2-5 amino acid residues or a single amino acid residue selected from Group 5, 2, or 4,

with the proviso, that when  $X^1$  includes Pro, then  $X^{19}$  is Gln.

In claim 1, applicants define the variable "X" as X can be an amino acid sequence or a single amino acid residue selected either from Group 1 consisting of Ala, Gly, and Ser, Group 2 consisting of Arg and Lys, Group 3 consisting of His, Ile, Leu, Met, Phe, Pro, Thr, Val, Trp, and Tyr, Group 4 consisting of Asn and Gln, or Group 5 consisting of Ala, Asn, Arg, Gln, Gly, His, Ile, Leu, Lys, Met, Phe, Pro, Ser, Thr, Trp, Tyr, Val. However, there is no variable "X" present in the formula as presented in claim 1. It is unclear and indefinite what this "X" variable with reference to the formula in claim 1.



In claim 1, applicants recite, “wherein,  $X^1$  can be represented by a sequence consisting of 2-5 amino acid residues or an amino acid residue selected from Group 2;  
 $X^2$  is selected from Group 5 or Group 3;  
 $X^3$ ,  $X^{15}$  and  $X^4$  are selected from Group 1;  
 $X^5$  is Thr or selected from Group 1;  
 $X^6$ ,  $X^{11}$ ,  $X^{12}$ ,  $X^{13}$  and  $X^7$  are selected from Group 3;  
 $X^8$  and  $X^{17}$  are selected from Group 1, 3 or 4;  
 $X^9$  is selected from Group 5, 1 or 3;  
 $X^{10}$  is selected from Group 2, 3 or 4;  
 $X^{14}$  is Set or selected from Group 3;  
 $X^{16}$  and  $X^{18}$  is selected from Group 1 or 3  
 $X^{19}$  can be represented by a sequence consisting of 2-5 amino acid residues or a single amino acid residue selected from Group 5, 2, or 4,  
with the proviso, that when  $X^1$  includes Pro, then  $X^{19}$  is Gln”.

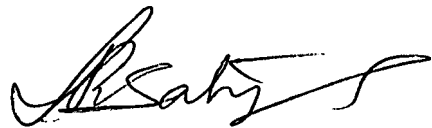
It is unclear whether the groups 1, 2, 3, 4, and 5 that define the variable “X” are the same groups that define the variables “ $X^1$  to  $X^{19}$ ” of the formula. Because, the claims does not recite limitations such as “said group 2” or “said group 3” when referring to variables  $X^1$  to  $X^{19}$ . It is unclear whether the groups that define variable “X” are the same or different groups that define variables “ $X^1$  to  $X^{19}$ ”. The claims as recited are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Satyanarayana R. Gudibande, Ph.D.  
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